

REMARKS

The present application is in response to an Office Action dated May 18, 2007. Claims 1-17, and 19-21 are pending. An amendment has been made in claims 1 and 12. Claim 18 has been cancelled. Claims 21 and 22 are new.

Amendment to Specification

The specification has been amended to correct two typographic errors. Figures 10 and 11, which were described as isometric views in the original specification, are more accurately described as plane views.

Objection to Drawings

The drawings are objected to under 37 CFR 1.83(a) because they do not show the distinction between progressive restriction in the flow channel, as claimed in claim 17, and monotonic restriction in the flow channel, as claimed in claim 18. Claim 18 has been cancelled. Progressive restriction in the cross-section of flow channel 216 along an axial direction 116, in flow reducing implant 370, is shown in Fig. 3E.

Claim Rejections – 35 U.S.C. 102**Claims 1-11**

Claims 1-11 stand rejected under 35 U.S.C. 102(b) as anticipated by US patent 6,013,055 to Bampas et al. Claim 1 has been amended, adding the limitation that the stave is made of a different material from the balloon. This is supported, for example, by page 7, lines 19-20, which state, "the balloon and/or one or more staves comprise materials configured to reduce in size to a compact profile". If the balloon and staves are not both comprised of such a material, but only one of them is, then they must be comprised of different materials. The ribs described by Bampas do not have this limitation, but are made of the same material as the balloon, as stated in col. 6, lines 15-19: "Longitudinal ribs 36 are formed in flexible material 24 of balloon 10 ... The term ribs is used herein to define an angle transition or change on the longitudinal surface of the balloon."

Since amended claim 1, at least, is patentable, claims 2-11 are patentable at least by virtue of their dependence on claim 1.

Claims 12-16 and claim 21

Claims 12-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,683,411 to Kavteladze et al, which shows an implant in Figs. 3, 4, 5 and 9 with a flexible band. Claim 12 has been amended to add the limitation that the flexible band surrounds a flow passage through which blood flows at a restricted rate, when the implant is implanted in a blood vessel. This limitation is supported, for example, by Fig. 5, which shows an implant 530 with a flexible band 502 surrounding a flow passage 216, as described on page 17, lines 26-28, and page 18, lines 1-2. These lines refer to the flexible band as a membrane wall. That the blood flow through passage 216 is restricted when implant 530 is implanted in a blood vessel is supported, for example, by page 17, line 24, which refers to implant 530 as a flow reducing implant.

Amended claim 12, at least, is not anticipated by Kavteladze, because the band in Figs. 3, 4, 5, and 9 of Kavteladze does not surround a flow passage through which blood flows at a restricted rate when the implant is implanted in a blood vessel. On the contrary, the implant shown in Figs. 3-5 of Kavteladze "is intended to function as a vessel occlusion device," stopping blood flow completely, according to col. 5, lines 10-12. Similarly, the device shown in Fig. 9 is "specifically designed for permanent complete occlusion of a part of the venous system," according to col. 6, lines 41-43.

Because amended claim 12 is patentable, claims 13-16 are patentable at least by virtue of their dependence on amended claim 12.

A new claim, claim 22, has been added, based on claim 12, but with the additional limitation that the staves are mounted around the outside of the band. This limitation is supported, for example, by Fig. 5, which shows staves 532, 534, 536, and 538 mounted on the outside of band (or membrane wall) 502, and by the description of Fig. 5 on page 17, lines 24-26, which state, "Fig. 5 is an isometric view of a staved type flow reducing implant...comprising staves 532, 534, 536 and 538 around a resilient membrane wall 502." Claim 21 is not anticipated by Kavteladze because, in Figs. 3, 4, 5, and 9 of Kavteladze, the structure which the Examiner identifies with the staves of claim 12 is

mounted on the *inside* of the band (element 16 in Figs. 3, 4 and 5, and element 42 in Fig. 9).

A new independent claim 21, has the limitations of old claim 12 and new claim 22.

Claims 17-20

Claims 17-20 stand rejected under 35 U.S.C. 102(b) as anticipated by US patent 6,120,534 to Ruiz. The applicant respectfully disagrees, because none of the devices described by Ruiz have all of the limitations of claim 17.

Claim 17 requires that the flow channel of the implant be sized for "blockage of substantially all blood-flow therethrough." Although Ruiz does describe an implant with a flow channel sized for reduced blood flow, he does not describe an implant as blocking substantially all blood flow. The Examiner cites col. 4, lines 60-67, of Ruiz as stating that the implant blocks substantially all blood flow. In fact, these lines state "...once stent 10 has been deployed in the pulmonary artery...The patient is then monitored for a period of time (i.e. sufficient for the flow to become stabilized) to assess whether the blood supply to the lungs is adequate with constricted region 13 at its maximum degree of flow constriction." Since, as is well known to those of skill in the art, all blood supply to the lungs flows through the pulmonary arteries, these lines can only mean that the implant does not block substantially all blood flow, but only reduces the blood flow. It is also known to those of skill in the art that if substantially all blood flow to the lungs were blocked, the patient would quickly die, so Ruiz's implant shown in Fig. 4B cannot be intended to block substantially all blood flow.

Claim 17 also requires that the flow channel have a cross-section which is progressively restricted along an axial direction. The Examiner states that this is true of the restricted region 13 in Ruiz's Fig. 2A. However, restricted region 13 in Fig. 2A, at least, is not progressively restricted along an axial direction, but becomes first more restricted, then less restricted, as one moves in an axial direction across it.

Claim 18 has been cancelled. Because claim 17 is patentable, claims 19 and 20 are patentable at least by virtue of their dependence on claim 17.

Claim 19 is also patentable for an additional reason. Claim 19 requires that the flow channel be sized to block at least 95% of the blood flow. The Examiner cites col. 3, lines 44-48 of Ruiz, as describing this limitation. However, these lines only state that the degree of restriction of the implant may be adjusted to selectively regulate blood flow. There is no suggestion in Ruiz that the blood flow should be reduced as much as 95%, or to a degree at all close to 95%. For at least some of the uses described by Ruiz for his implants, for example in the pulmonary artery as described on col. 4, lines 60-67, quoted above, it is evident that blocking at least 95% of the blood flow would quickly lead to the death of the patient. Furthermore, the drawings of the various implants shown in Ruiz all show a reduction in diameter of the flow passage of the blood vessel of approximately a factor of 2, at the most constricted part of the implant. Although these drawings may not be to scale, they also suggest only a moderate reduction in blood flow, not even close to 95%.

In view of the above remarks, applicants submit that the claims are patentable over the prior art.

Respectfully submitted,



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Enclos:

- Petition for Extension (Three Months)
- Additional Claims Transmittal Fee